DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Vital Images, Inc.
% Parthiv Shah
Sr. Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

March 5, 2015

Re: K150258
Trade/Device Name: Vitrea®, Version 7.0 Medical Image Processing Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 4, 2015
Received: February 5, 2015

Dear Parthiv Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150258

Device Name

Vitrea® , Version 7.0 Medical Image Processing Software

Indications for Use *(Describe)*

Vitrea is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea is not meant for primary image Interpretation in mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92(c)

Purpose of Submission:	Vital Images, Inc. hereby submits this special 510(k) to provide a notification submission for proposed software changes in the already 510(k) cleared Vitrea software (K071331).
Submitter:	Vital Images, Inc. 5850 Opus Parkway Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Parthiv Shah Sr. Regulatory Affairs Specialist Phone : 952–487–9574 Fax: 952–487–9510 E-mail: pshah@vitalimages.com
510(k) Type:	Special
Summary Date:	February 3, 2015
Device Trade Name:	Vitrea, Medical Image Processing Software
Other Device Trade Names:	Vitrea Enterprise Suite, VitreaCore, VitreaAdvanced, VitreaAdvanced fX, VitreaWorkstation, VitreaWorkstation fX, VitreaExtend
Device Common Name:	Radiological Image Processing Software
Device Classification Name:	System, Image Processing, Radiological
Regulatory Description:	Picture Archiving and Communications System
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology

Predicate Device:

Predicate Device	Manufacturer	FDA 510(k) number
Vitrea, Medical Image Processing Software, Version 4.0 (Legally Marketed Device)	Vital Images, Inc.	K071331

Device Description:
Vitrea is a medical diagnostic system that allows the processing, review, analysis, communication, and media interchange of multi-dimensional digital images acquired from a variety of imaging devices.

The Vitrea system provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The Vitrea user interface follows typical clinical workflow patterns to process, review, and analyze digital images, including:

- Retrieve image data over the network via DICOM
- Display images that are automatically adapted to exam type via dedicated protocols
- Select images for closer examination from a gallery of up to six 2D or 3D views
- Interactively manipulate an image in real-time to visualize anatomy and pathology
- Annotate, tag, measure, and record selected views
- Output selected views to standard film or paper printers, or post a report to an intranet web server or export views to another DICOM device
- Retrieve reports that are archived on a Web server

Intended Use / Indications for Use:
Vitrea is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea is not meant for primary image interpretation in mammography.

Scope of Changes:
Vital Images is replacing / updating some components of Vitrea platform to utilize enhancements in software technology for better performance of the Vitrea software.

Software Platform Components:

#	Replaced Software Component (Version 7.0)	Rationale for Changes
1	**Product Infrastructure** It is a collection of non-clinical applications that work on top of the platform to provide common functions and assist with overall workflow.	Redesigned for better user experience and support for web-based applications.

#	Replaced Software Component (Version 7.0)	Rationale for Changes
	New Components: **Vitrea Client (AppShell):** Launches other applications and embeds the applications within a common window. Hosts product applications that allow the users to view the Study List and launch various applications with DICOM data. **Study List:** Displays the list of patient data received from DICOM modalities, associated evidence for patient studies, and available applications to load data into.	
2	**Vitrea Services Platform (VSP)** It is a basic service platform for managing patient data, applications, licensing, and configurations. Enhanced features: **Application Management:** Application Management is a key feature of the platform, which is designed to let applications be installed, registered, and licensed independently of the platform. The AppManager component is also responsible for lifecycle management (startup and shutting down idle/abandoned sessions) for launched applications. **User Management:** User Management provides authentication and authorization, auditing, user preferences, roles & group management. These can be configured directly within the platform, or integrated to external user management systems such as Active Directory. **Data Access:** Data Access features include DICOM search, evidence management, temporary data management, UID generation, and session save/restore. **Systems Management:** Systems Management consists of system settings, configuring DICOM endpoints, installing licenses, and configuring network security settings.	Redesigned to improve manageability and simplify application integration.

#	Replaced Software Component (Version 7.0)	Rationale for Changes
	Workflow: Workflow is an anticipatory processing feature which allows applications to register for and perform batch processing when new data arrives; for example extracting data from structure reports, generating alternate representations (e.g. MPR projections, bone removal), image analysis.	
3	**CPU-Based Rendering Engine** A CPU-based rendering engine performs rendering using CPU only. It does not require a GPU card to be present on the system. In order to support deployments those do not have GPU hardware or do not have access to GPU hardware, such as virtual deployments, it is important to have a CPU-based rendering engine. New Component: We have introduced an additional CPU-based rendering engine. It is a software-based rendering engine used for rendering patient data in clinical applications.	Newly added rendering engine for CPU rendering support use for virtual deployments.
4	**DICOM Cache** This component keeps a local copy of DICOM images received from PACS and/or modalities in order to provide fast access for user applications to enable a good user experience. New Components: **Vitrea Information Management System (VIMS):** The VIMS is the communicator to the world outside the Vitrea station. It connects to other systems via the DICOM standard. VIMS is a separate process running on the Vitrea station that is independent of the Vitrea application. Communication to and from VIMS is done via Web Services. The key features are DICOM receive (multi-byte data set support), DICOM Export, Volume building, and DICOM print. **MINT:** The Medical Imaging Network Transport (MINT) protocol is a server component for accessing DICOM data through web services.	Replaced the old ECF component for better user experience and improved functionality.

Software Deployment:

#	New Deployment (version 7.0)	Reason for Changes
5	**Multiple User Workstation Deployment** New Deployment: Multi-user multi-modality departmental deployment of the workstation, which allows multiple concurrent user access to the workstation at the same time without degrading the performance.	To extend the capabilities of the workstation to multiple (currently up to 3) concurrent users.

Intended for Disease / Condition / Patient Population:
Vitrea system is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Therefore intended disease, conditions, or patient population information is not applicable.

Substantial Equivalence Comparison:

- **Regulatory Comparison**

Criteria	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Device Type / Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Common Name	Radiological Image Processing Software	Radiological Image Processing Software	Same
Regulation / Classification Number	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	LLZ	LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same

- **Intended Use Comparison**

Criteria	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Indications for Use	Vitrea is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea is not meant for primary image interpretation in mammography.	Vitrea is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea is not meant for primary image interpretation in mammography.	Same

- **Device Description Comparison**

Device Description	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
General Description:			
The Vitrea system is a medical diagnostic device that allows the processing, review, analysis, communication, and media interchange of multi-dimensional digital images acquired from a variety of imaging devices.	**Same**	**Same**	**Same**

Device Description	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
The Vitrea system provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology.	**Same**	**Same**	**Same**
The Vitrea system user interface follows typical clinical workflow patterns to process, review, and analyze digital images.	**Same**	**Same**	**Same**
Key Features:			
Retrieve image data over the network via DICOM.	**Same**	**Same**	**Same**
Display images that are automatically adapted to exam type via dedicated protocols.	**Same**	**Same**	**Same**
Select images for closer examination from a gallery of up to six 2D or 3D views.	**Same**	**Same**	**Same**
Interactively manipulate an image in real-time to visualize anatomy and pathology.	**Same**	**Same**	**Same**
Annotate, tag, measure, and record selected views.	**Same**	**Same**	**Same**
Output selected views to standard film or paper printers, or post a report to an intranet Web server or export views to another DICOM device	**Same**	**Same**	**Same**
Retrieve reports that are archived on a Web server.	**Same**	**Same**	**Same**

- **Similarities in Technology**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
General Features:			
Selection and loading a patient study **Component**: "Study Directory" (old name) / "AppShell / Vitrea Client and Study List" (new name)	**Same**	**Same**	**Same**
Selection of protocol and preset for patient study **Component:** Gallery Window	**Same**	**Same**	**Same**
Visualization and analysis of patient study **Component:** Viewer Window	**Same**	**Same**	**Same**
Allows access to the visual, analysis, and batch pages **Component:** Viewer Window	**Same**	**Same**	**Same**
Segment, trim, sculpt, perform measurements, and change display settings **Component:** Viewer Window	**Same**	**Same**	**Same**
Record images, batches of images, and movies for physician reporting **Component:** Viewer Window	**Same**	**Same**	**Same**
Creation of a report for the patient study) data publishing and archiving **Component:** Report Window	**Same**	**Same**	**Same**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Review of report for any patient study **Component:** Report Window	**Same**	**Same**	**Same**
Help on Vitrea software **Component:** Help Window	**Same**	**Same**	**Same**
DICOM Compliance and Data Management	**Same**	**Same**	**Same**
Data Security and HIPAA Compliance	**Same**	**Same**	**Same**
Picture Achieving and Communication System (PACS) Information Sharing	**Same**	**Same**	**Same**
Multi-vendor scanner compatibility	**Same**	**Same**	**Same**
Integrated 2D and 3D visualization measurements	**Same**	**Same**	**Same**
Interactive navigation in 3D	**Same**	**Same**	**Same**
Large data set capability, including the ability to render multi-detector computed tomography (MDCT) data	**Same**	**Same**	**Same**
Multi-modality Support	**Same**	**Same**	**Same**
Vitrea Basic Clinical Toolset:			
Retrieve image data over the network	**Same**	**Same**	**Same**
Display images that are automatically adapted to exam type via dedicated protocols	**Same**	**Same**	**Same**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Select images for closer examination from a gallery of up to six 2D or 3D views	**Same**	**Same**	**Same**
Interactively manipulate an image in real-time to visualize anatomy and pathology	**Same**	**Same**	**Same**
Annotate, tag, measure, and record selected views	**Same**	**Same**	**Same**
Output selected views to standard film or paper printers, or post a report to an Intranet	**Same**	**Same**	**Same**
Study List (old name- Study Directory Window):			
Automatic reading and display of demographic and scanner information including Patient, ID, Date, Time, Series, Modality, Exam Type, Thickness/Spacing, and the number of images in the series	**Same**	**Same**	**Same**
Each patient entry can include multiple series of image data	**Same**	**Same**	**Same**
Fully sortable listing of all studies present on the system to optimize data searching and selection for users, along with user-specific filters	**Same**	**Same**	**Same**
Preview of an image of the selected series to ensure its applicability	**Same**	**Same**	**Same**
Customization of the layout of study list to each user's personal preference	**Same**	**Same**	**Same**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Series thumbnail display indicating available series	**Same**	**Same**	**Same**
Display of selected images, series, or entire study and loading of multiple series or studies for simultaneous analysis and review	**Same**	**Same**	**Same**
Direct launch into 2D or 3D workflow for a study or series	**Same**	**Same**	**Same**
Display image findings and reports in the Evidence Manager	**Same**	**Same**	**Same**
Retrieve reports that are archived on a Web server	**Same**	**Same**	**Same**
Gallery Window:			
Unique clinical protocols based on anatomy, workflow, and image type	**Same**	**Same**	**Same**
Automatic pre-selection of clinical protocol of images to exam type, as indicated in the DICOM header fields	**Same**	**Same**	**Same**
Easy selection of up to six independent 2D and 3D views of selected image data for review, optimized and rendered based on the clinical protocol	**Same**	**Same**	**Same**
Ability to return to the Gallery window at any time to select other views, or to select alternative protocols	**Same**	**Same**	**Same**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Customized presets that can be created in the Viewer window for display and selection in the Gallery window (one custom preset for each view available for any of the protocols)	**Same**	**Same**	**Same**
Viewer Window:			
A choice of four 2D review and four 3D display formats, as well as a 2D "All Exams" comparative viewer that allows the user to display up to nine series on the screen at once	**Same**	**Same**	**Same**
Pick tabs in both 2D comparative and 2D montage formats, allowing the user to change the orientation of the image views and the order of the series displayed in comparative viewing	**Same**	**Same**	**Same**
Simultaneous view of 3D volume-rendered projections and correlated multi-planar reformatted projections (MPRs)	**Same**	**Same**	**Same**
Orthogonal, Oblique, Double Oblique, and Curved MPRs	**Same**	**Same**	**Same**
Cross-reference lines (Crosshairs) to identify and correlate point of interest in all 2D and 3D views	**Same**	**Same**	**Same**
Ability to navigate, scroll, pan, cine, zoom, rotate, flip, invert interactively that lets the user select, edit, measure, annotate, and record the optimum 2D and 3D views for diagnosis and reporting	**Same**	**Same**	**Same**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Navigation through or around the 3D view selected (Fly-around, Fly-through, Point-of-interest)	**Same**	**Same**	**Same**
Adjustment of window/level on screen interactively	**Same**	**Same**	**Same**
Adjustment of a broad range of imaging controls and displays such as rendering (Normal, Min/Max Intensity Projections), brightness, contrast, shading, transparency, and color	**Same**	**Same**	**Same**
Image segmentation using any of several segmentation methods (trimming, freehand/box sculpting, semi-automated vessel inclusion/bone removal based on threshold and connectivity)	**Same**	**Same**	**Same**
Variable size slab reformat and rendering	**Same**	**Same**	**Same**
Annotation of the images with embedded 3D arrows and text	**Same**	**Same**	**Same**
Distance measurements using ruler and area and volume measurements using ellipse or freehand ROI	**Same**	**Same**	**Same**
Keyboard shortcuts for many functions	**Same**	**Same**	**Same**
Creation of custom visualization presets to appear in the Gallery Tab	**Same**	**Same**	**Same**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Recording of selected views (snapshots) for report generation and to allow return to the same view at a later time to continue the work done previously; ability to record a multi-volume snapshot for cases when multiple series or volumes have been loaded simultaneously	**Same**	**Same**	**Same**
Batch creation functionality that allows 2D, 3D, or 3D fly through batched images or movies to print or be sent to the report page	**Same**	**Same**	**Same**
Report Application:			
Report configuration in 1-on-1,4-on-1, 9-on-1, 12-on-1, 16-on-1, 20-on-1 and 24-on-1 image formats	**Same**	**Same**	**Same**
Report header that includes user configurable information such as Institution Name, Patient ID, Patient Name, Referring Physician, Reading Physician, Exam Type, Modality, Scan Date, and Scan Time	**Same**	**Same**	**Same**
Inclusion or deletion of patient and hospital information for filming purposes	**Same**	**Same**	**Same**
Slide Tray containing snapshots, batches, and movies saved in the Viewer window	**Same**	**Same**	**Same**
Snapshot restoration	**Same**	**Same**	**Same**
Movie preview	**Same**	**Same**	**Same**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Electronic posting of reports to a Web server	**Same**	**Same**	**Same**
Printing of the report on DICOM or Postscript® format printers, exporting to a DICOM image archive, posting on Vitrea software's web server, recording on a CD or a DVD, or exporting to a MS Word document with a defined template	**Same**	**Same**	**Same**
Evidence Manager (old name- Review Window):			
Allows the user to view published Image / batch finding reports and related digital movies	**Same**	**Same**	**Same**
Help Window:			
Provides on-line help manual, quick reference and index in HTML format or as PDF documents	**Same**	**Same**	**Same**
DICOM Data Management:			
DICOM conformance	**Same**	**Same**	**Same**
DICOM Storage as SCU & SCP (receive and push)	**Same**	**Same**	**Same**
DICOM query/retrieve SCU (pulling images from other DICOM devices)	**Same**	**Same**	**Same**
DICOM query/retrieve SCP (can serve images to other vendor workstations)	**Same**	**Same**	**Same**
DICOM Connection Management	**Same**	**Same**	**Same**

Software Functionality	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Comparison
Save & Send images in DICOM	**Same**	**Same**	**Same**
PACS Interface:			
Provides an API targeting PACS vendors for usage, and a new level of integration in which Vitrea data can be automatically (or more easily) stored back to the PACS station	**Same**	**Same**	**Same**
Data Security and HIPAA Compliance:			
Software can de-identify patient data, removing patient name and information from the image	**Same**	**Same**	**Same**
Software controls workstation access and reporting security	**Same**	**Same**	**Same**
Authentication and access controls require users to enter a confidential password to view both patient studies and reports	**Same**	**Same**	**Same**
An audit log automatically records user access, privilege, and operations	**Same**	**Same**	**Same**
Secured access (NT or domain -Login)	**Same**	**Same**	**Same**
User group preference and access control	**Same**	**Same**	**Same**

- **Differences**

Difference	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Rationale for Changes	Comparison
Product Infrastructure It is a collection of non-clinical applications that work on top of the platform to provide common functions and assist with overall workflow. Functionality: Retrieve and load image data over the network or from datasets previously uploaded to the workstation.				
Difference: Replacement of software component. **Note:** Only component is replaced, no change in basic functionality.	**Study Directory:** The Study Directory window lets the user retrieve and load image data over the network or from datasets previously uploaded to the workstation.	**Vitrea Client:** It launches other applications and embeds the applications within a common window. It hosts application for the product that allows the user to view the Study List and launch various applications with DICOM data. **Study List:** It displays the list of patient data received from DICOM modalities, associated evidence for patient studies, and available applications to load data into.	Replaced the old "Study Directory" component for better user experience and support for web-based applications.	The replacement does not affect the intended use or fundamental scientific technology of already cleared Vitrea software (K071331).

Difference	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Rationale for Changes	Comparison
Vitrea Services Platform (VSP) It is a basic service platform for managing patient data, applications, licensing, and configuration. Functionality: Managing patient data, applications, licensing, and configuration.				
Difference: Redesign of software component. **Note:** No change in basic functionality.	**Vitrea Services Platform:** It is a basic service platform for managing patient data, applications, licensing, and configuration.	**Modified Vitrea Services Platform:** It is a basic service platform for managing patient data, applications, licensing, and configuration. Enhanced features: • Application Management • User Management • Data Access • System Management • Workflow	Redesigned to improve manageability and simplify application integration.	The replacement does not affect the intended use or fundamental scientific technology of already cleared Vitrea software (K071331).
CPU-Based Rendering Engine Functionality: A CPU-based rendering engine performs rendering using CPU only. It does not require a GPU card to be present on the system. In order to support deployments that do not have GPU hardware or do not have access to GPU hardware, such as virtual deployments, it is important to have a CPU-based rendering engine.				
Difference: Addition of new CPU-based rendering engine.	No CPU rendering support. Note: Vitrea 4.0 had only GPU rending support.	New Component: We have introduced an additional CPU-based rendering engine. It is a software-based rendering engine used for rendering patient data in clinical applications.	Newly added rendering engine for CPU rendering support use for virtual deployments.	The CPU rendering engine was designed to mirror the behavior of the GPU rendering in both image quality and performance.

Difference	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Rationale for Changes	Comparison
				Although they are not identical, the differences are mostly cosmetic and do not affect the intended use or fundamental scientific technology of already cleared Vitrea software (K071331).
DICOM Cache Functionality: This component keeps a local copy of DICOM images received from PACS and/or modalities, in order to provide fast access for user applications to enable a good user experience.				
Difference: Replacement of software component. **Note:** Only component is replaced, no change in basic functionality.	**External Communications Framework (ECF):** The ECF is the communicator to the world outside the Vitrea Workstation. It connects to other systems via the DICOM standard. ECF is a separate process running on the Vitrea Workstation that is independent of the	**Vitrea Information Management System (VIMS):** The VIMS is the communicator to the world outside the Vitrea Workstation. It connects to other systems via the DICOM standard. VIMS is a separate process running on the Vitrea Workstation that is independent of the Vitrea application.	Replaced the old ECF component for better user experience and improved functionality.	The replacement does not affect the intended use or fundamental scientific technology of already cleared Vitrea software (K071331).

Difference	Legally Marketed Device Vitrea, Medical Image Processing Software, version 4.0 (K071331) (Predicate Device)	Modified Subject Device Vitrea, Medical Image Processing Software, version 7.0	Rationale for Changes	Comparison
	Vitrea application. Communication to and from ECF is done via inter-process messages (through a CORBA-based interface) and not direct calls to binary code.	Communication to and from VIMS is done via Web Services. The key features are DICOM receive (multi-byte data set support), DICOM Export, Volume building, and DICOM print. **MINT:** The Medical Imaging Network Transport (MINT) protocol is a server component for accessing DICOM data through web services.		
Multiple User Workstation Deployment				
Difference: Addition of type of software deployment.	No Multiple User workstation support	**Multiple User Workstation Deployment** New Deployment. Multi-user multi-modality departmental deployment of the workstation, which allows multiple concurrent user access to the workstation at the same time without degrading the performance.	To extend the capabilities of the workstation to multiple users.	The addition of new deployment does not affect the intended use or fundamental scientific technology of already cleared Vitrea software (K071331).

Summary of Non-Clinical Tests:
The changes to the Vitrea software were designed, developed, and tested according to written procedures that included applying risk management. Software testing was completed to ensure the new feature operates according to its requirements.

The following design control measures were applied to the development of the Vitrea Software:

- Risk Management
- Requirements Reviews
- Code Designs
- Code Development Testing
- Code Reviews
- Design Reviews
- Verification of the Software

Risk Management:
Each risk pertaining to these modifications has been individually assessed to determine if the benefits outweigh the risk. Every risk has been reduced as low as possible. Based on Post Market information and because of the risk control measures included in these modifications, it is believed that the risk for these modifications as a whole is extremely low.

Verification:
The software verification team's primary goal was to assure that the software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As a part of creating the test cases, the verification team reviewed and monitored the Requirements Traceability Matrix ("RTM") to ensure coverage of the items within the RTM.

Summary of Clinical Tests:
The subject of special 510(k) notification, Vitrea software, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

- ***Confidentiality***
  The Vitrea platform relies on built-in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.

- ***Integrity***
  The Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. New DICOM produced by Vitrea is identified as such with the appropriate manufacturer tags per the DICOM standard.

- ***Availability***
  The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.

- ***Accountability***
  The Vitrea platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Performance Standards:
The FDA has not established mandatory performance standards and no special controls exist for this device. General software verification and validation tests were conducted to confirm proper function of the device's features.

The Vitrea software complies with the following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

Substantial Equivalence Analysis Conclusion:
The minor software enhancements do not affect the intended use or alter the fundamental scientific technology of legally marketed Vitrea software (K071331). The modified Vitrea software has the same indications for use, principle of operation, and performs the same technological functions as already cleared Vitrea software - K071331 (Predicate Device). The modifications are not consequential from the standpoint of device operation, safety, effectiveness or intended use.

Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness when used as labeled. The implemented design mitigations, labeling, and the performed verification and validation tests demonstrate the safety and efficacy of the device is equivalent to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device.